APPENDIX N BULK MILK TANKER SCREENING TEST FORM

GENERAL REQUIREMENTS
(Unless otherwise stated all tolerances ±5%)

1. Work Area _____

a. Ample working space and utilities _____

b. Clean well ventilated, test kit used in temperature range specified by manufacturer, reasonably free from dust and drafts _____

c. Adequate lighting, **[NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, > 50 foot-candles at working surface (pref 100)]** _____

2. Storage Space _____

a. Cabinets, drawers, and shelves adequate _____

b. Areas neat, clean and orderly _____

3. Thermometers for Use with Test Kits and Laboratory Equipment _____

a. Thermometer traceable to NIST Certified thermometer _____

1. Traceable thermometer checked at ice point annually _____

b. Range of thermometers appropriate for designated use _____

c. Graduation interval not greater than 1.0C **[NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, 0.5C]** _____

d. Accuracy of test thermometers checked against traceable thermometer annually (including electronic thermometers) _____

1. Accurate to ±1C _____

2. Results recorded and thermometers tagged with date, identification, temperature checked and correction (±0.0 if none) _____

3. Thermometers calibrated on-site _____

4. Thermometers calibrated at another location _____

a. Location calibrated: _____ _____

b. Calibrations current and acceptable _____

c. Copy of calibration record on-site _____

e. Records maintained _____

f. Dial thermometers not permitted _____

4. Refrigeration _____

a. Size adequate for workload _____

b. Maintains samples at 0-4.4C _____

c. Reagents stored as per manufacturer instructions _____

d. Not used to store food or drink for consumption _____

e. Record temperature daily from 2 thermometers with bulbs submerged in liquid, placed on upper and lower shelves of use **[NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, AM and PM]** _____

f. **NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, dedicated for milk work only, NO PATHOGENS STORED** _____

5. Freezer _____

a. Size adequate for workload _____

b. Maintains -15C or below _____

c. Not used to store food or drink for consumption _____

d. Record temperature daily from thermometer with bulb submerged in anti-freeze liquid, **[NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, AM and PM]** _____

e. **NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, dedicated for milk work only, NO PATHOGENS STORED** _____

6. Balance, electronic (if necessary) _____

a. Weight capability appropriate for intended use _____

b. Accurate to 0.01g for preparations of positive controls _____

c. Appropriate sensitivity for calibration of pipetting devices within a tolerance of ±5% (0.001g sensitivity appropriate in most instances) _____

d. Checked monthly with Class S or S1, or equivalent ASTM 1, 2, or 3 weights **(Appendix N drug testing only laboratories may check every 6 months)** _____

e. Checked annually by a qualified service representative_____

f. Records maintained _____

7. Pipettors, calibrated, fixed volume or electronic only [Required for NCIMS Certified Laboratories and Certified Industry Supervisors] _____

a. Calibrate with ten (10) consecutive measurements, by weight or by volume (>1.0 ml using a class A graduated cylinder), using separate tip for each measurement, every 6 months _____

b. Average of all 10 measurements must be ±5% of specified delivery volume, records maintained _____

c. Or, calibrate with 10 consecutive readings once every 6 months using the Artel PCS Pipette Calibration System, average of all 10 readings Must be ±5% of specified delivery volume, records/ printouts maintained _____

1. Instrument, printer connected by manufacturer supplied cable or instrument connected to computer via serial cable _____

2. Instrument and printer (if applicable) connected to 120v/60Hz power _____

3. Reagent kits and Instrument Calibrator kits stored at room temperature _____

a. Lot # _____ Exp. Date _____ _____

4. Reagent Blanks and Sample Solutions are the same lot _____

5. Certificates of Calibration for Reagent Kit and Instrument Calibrator kit maintained in records _____

6. Instrument Validation Guide available _____

7. PCS Pipette Calibration System Procedure, follow manufacturer’s Procedure Guide and instrument prompts _____

a. Uncover and insert Blank into the instrument _____

b. Determine which volumes are to be calibrated _____

c. Select the correct Sample Solution and aliquot sufficient amount into working vessel provided _____

d. Using the Pipettor to be verified, aspirate the Sample Solution from the working vessel and deliver it into the Blank seated in the instrument _____

e. When appropriate number of measurements are collected, press ‘End of Run’ button _____

f. Record results and file Pipette Calibration Certificate (printout) _____

8. PCS Pipette System Quality Control _____

a. Following manufacturer’s Procedure Guide and instrument prompts, perform an instrument calibration every 30 days or just prior to use _____

b. Record results and file Calibration Certificate (printout) _____

9. PCS Calibration System Validation, upon receipt, validate the instrument by following the manufacturer’s protocol _____

d. Pipettors etched with identification (imprinted serial numbers acceptable) and tagged with date calibrated _____

e. Appropriate tips for pipettor(s) used _____

f. Pipetting devices calibrated on-site _____

g. Pipetting devices calibrated at another location _____

1. Location calibrated: _____ _____

2. Calibrations current and acceptable _____

3. Copy of calibration record on-site _____

h. Records maintained _____

8. Deionized Water or Equivalent, or as specified by manufacturer _____

SAMPLES

9. Sample Requirements _____

a. Prevent contamination with disinfectants from hands or other sources _____

b. Ascertain temperature of bulk milk tanker _____

c. If sample will not be tested without delay then a temperature control (TC) sample must be taken, transported and maintained with the tanker sample until it is tested _____

d. Secure a representative sample for drug residue testing and transport to testing location promptly, preferably on ice to maintain temperature _____

e. Tanker samples tested promptly upon arriving at the testing location, measure TC when provided _____

1. Temperature of bulk milk tanker may be used for temperature as received and tested if sample testing begins without delay _____

2. If test kit indicates a positive result, confirmation completed (when necessary) within 72 hours of initial collection _____

f. Record time, date and temperature of samples as received and tested _____

g. Determine sample temperature by inserting pre-cooled thermometer (pre-cooling of electronic/digital thermometer probes is not necessary) into temperature control (TC), if no TC, aliquot samples for testing and measure temperature using one of the producer samples _____

h. Do not accept producer samples (about ¾ full) that are over filled _____

i. If raw milk exceeds 4.4C on receipt do not test (samples may be received at 7C if time of receipt is Ω3 hours from collection and arrival temperature is equal to or less than temperature of collection) _____

PERFORMANCE TESTING

10. Performance Testing _____

a. Run a positive and negative control before use on each new lot of kits, must give appropriate results, records maintained _____

b. Run a negative and positive control **DAILY** (on days testing), at each test site, must give appropriate results, if not, re-run controls (may be necessary to prepare new controls), if problem persists discontinue testing, contact State regulatory and seek technical assistance, records maintained _____

c. If available from manufacturer, check instrument calibration with check devices **DAILY** (on days testing), must give appropriate results, if not, discontinue testing and seek technical assistance, records maintained _____

d. If more than one analyst performs analysis, have different analyst run performance check on rotational basis _____

FOLLOW-UP ON TEST KIT POSITIVE RESULTS
[Must comply with M-a-86, current revision]

11. Verification of Initial Positive Tanker Samples _____

a. The **SAME** sample is re-tested by the **SAME** analyst using the **SAME** test kit in **DUPLICATE** along with a positive and negative control _____

b. Positive and negative controls give the appropriate result(s) _____

c. If one or both duplicates is positive the tanker sample is **PRESUMPTIVE POSITIVE** and the sample is referred to the designated certified laboratory or Certified Industry Supervisor (CIS) as specified by the facility's protocol as per Agreement with the State Regulatory Agency _____

d. Presumptive positive samples must be forwarded to a certified laboratory, not tested by screening facility; producer samples must be tested by a certified laboratory _____

e. If both duplicates are negative milk may be received and processed, record and report as **NOT FOUND** _____

f. If positive and/or negative controls do not give appropriate results, re-run controls and samples. If problem persists seek technical assistance _____

g. Complete Positive report form and maintain records of all analyses _____

1. For Presumptive Positive samples maintain a copy of the positive report form and forward the original to the certified laboratory or CIS _____

12. Confirmation of Presumptive Positive Tanker Samples _____
[Only in a certified laboratory or by a CIS (refer to M-a-85 current revision for listing of test kits to assure equivalence)]

a. The **SAME** sample **[or if it can be demonstrated that the original sample is suspect, a re-sample may be used at the State's discretion]** is tested in **DUPLICATE** along with a positive and negative control _____

b. Positive and negative controls give the appropriate result(s) _____

c. If one or both duplicates is positive the tanker sample is **CONFIRMED POSITIVE**, milk may not be processed, contact State Regulatory _____

d. Producer trace back performed on all producer samples from the load, see item 13 _____

e. If both duplicates are negative milk may be received and processed, record and report as **NOT FOUND,** producer trace back is not performed _____

f. If positive and/or negative control do not give appropriate results, re-run controls and samples, if problem persists seek technical assistance _____

g. Complete Positive report form and maintain records of all analyses _____

1. For Confirmed Positive samples maintain a copy of the positive report form and forward the original to the State Regulatory Agency _____

13. Trace back of Producers on a Confirmed Positive Tanker _____
[Only performed in a certified laboratory or by a CIS (refer to M-a-85 current revision for listing of test kits to assure equivalence), this process is also to be followed when doing PMO Section 6 analyses for drugs]

a. Perform an initial single test on each producer sample along with a single positive and negative control for the series _____

b. Positive and negative controls give the appropriate result(s) _____

c. If any producer sample is positive the sample is **SUSPECT** and that/those sample(s) must be re-tested _____

d. The **SAME** sample is re-tested by the **SAME** analyst using the **SAME** test in **DUPLICATE** along with a positive and negative control _____

e. Positive and negative controls give the appropriate result(s) _____

f. If one or both duplicates is positive the producer sample(s) is (are) **POSITIVE** _____

g. If both duplicates are negative record and report the appropriate producer sample(s) **NOT FOUND** _____

h. If positive and/or negative control do not give appropriate results, re-run controls and samples, if problem persists seek technical assistance _____

i. Complete Positive report form and maintain records of all analysis _____

1. For Confirmed Producer Positive samples maintain a copy of the positive report form and forward the original to the State Regulatory Agency _____

REPORTING AND RECORDS

14. Reporting and Records _____

a. Report as **Positive** (+) for beta-lactam, specific drug or inhibitor (when a non-specific microbial inhibitor test used without beta-lactamase) when demonstrated _____

b. Report as **Not Found (NF)** when demonstrated _____

c. Record test performed, interpretation of unknowns (samples) and controls _____

d. Records, including all printouts, maintained for 2 years _____

MISCELLANEOUS

15. Miscellaneous _____

a. Material safety data sheets (MSDS) on file _____

b. Current, applicable survey forms available in laboratory _____

c. Positive Report Forms available with instructions _____

d. Personnel adequately trained _____

e. Required split/check sample participation _____